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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,379	12/05/2000	Ronit Simantov	955-7P/CON	7403

23869 7590 03/18/2003

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/18/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,379

Applicant(s)

SIMANTOV ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 32-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 32-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Claims 2, 3, and 32-45 are pending and examined on merits.

Claim Rejections - 35 USC § 112

Rejection of the claims under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** because of the current state of art along with the teachings of instant specification, it is concluded that it does not require undue experimentation to figure out what which part(s) of the protein recited in claims have the functional properties recited in the claim.

Claims **2 and 3 remain rejected**, and claims **32, and 34 are also rejected** for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. Applicant argues that the specification teaches several methods for assaying the claimed proteins and it is well within the capacity of the artisan to determine the thrombospondin-binding activity of the proteins of the invention. This argument is not convincing because the Office interprets the instant claims as drawn to a genus of proteins called HRGP. The specification provides evidence for only one such protein from human but does not describe the structural characteristics of other HRGPs such as one from pig, dog, etc. Based on only one

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species, one cannot predict the types of additional species. Since the genus includes a large number of unpredictable species, possession of only species is not seen as sufficient to reasonably convey possession of the entire genus. It is concluded that applicants adequately describes the HRGP from human.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

Claims 2, 3, and 32-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to **use** the invention. The claims are interpreted as drawn to a pharmaceutical comprising HRGP. This rejection is based on the limitation "pharmaceutical" in the instant claims. Inherent in pharmaceutical is in vivo use. The entire specification (see Figs 1-3 and Examples at pages 41-55) is about the specific structure responsible for binding of the well known protein called HRGP (sequenced by Koide et al, 1986, Biochemistry, vol. 25, pages 2220-2225) to thrombospondin, thereby antagonizing the anti-angiogenic effect of TSP-1. The specification does not teach what disease(s) could be treated using the instant invention. The art recognizes in vivo treatment is not a trivial matter and Simantov et al (J. Clin. Invest. Vol. 107, pages 45-52) teach that using HRGP as pharmaceutical is still in research and development process. Considering the state of art and the limited teaching of the specification about what disease(s) should be treated with the claimed pharmaceutical with what protocols, it is concluded that one skilled in the art would have reasons to question the efficacy of

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the claimed pharmaceutical for treating any disease. In the absence of working example or other evidence of the pharmaceutical's effectiveness for any disease, it is concluded that undue experimentation would be required to practice the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, and 32-45 are rejected under 35 U.S.C. 102(b) as being anticipated by either Koide et al (abstract only, 1986, Biochemistry, vol. 25, pages 2220-2225), or Saigo et al (1989, J. Biol. Chem. vol. 264, pages) as evidenced by GenBank accession number P04196 (06-15-2002).

The instant claims are interpreted as drawn to protein per se and Koide et al teach the entire human 525 amino acids human HRGP protein sequence and instant SEQ ID NOs 1-13 are peptides sequences within the full length HRGP. Since the instant claims recite "comprises", the instant claims read on the protein of prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
March 16, 2003


SHEELA HUFF
PRIMARY EXAMINER